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10/553,298

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Nicholas Barden

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

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DELIVERY MODE

08/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/553,298 | <b>Applicant(s)</b><br>BARDEN ET AL. |  |
|                              | <b>Examiner</b><br>Michael Pak       | <b>Art Unit</b><br>1646              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group XVII in the reply filed on May 2, 2008 is acknowledged. The traversal is on the ground(s) that Group VII and XVII are not clearly explained. The restriction has been recast as below. Group VII now has claims 25-27 and 55-56 as drawn to DNA sample analysis or PCR analysis of DNA. Group XVII is now drawn to claims 25-27 as they read on immunological analysis or protein analysis. Group XVIII is drawn to RNA analysis. The restriction to Markush group has been changed to be drawn to any claims which encompass mutants.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 13, 20-22, 32, 46 drawn to an isolated and purified polynucleotide, an expression vector, a host cell, a method for producing a polypeptide, classified in Class 435, subclass 69.1.

II. Claims 14, 20-22, 46, drawn to a polypeptide, classified in Class 530, subclass 350.

III. Claim 15-16, 20-22, 46, drawn to a purified antibody, classified in Class 435, subclass 387.1.

IV. Claim 17, 20-22, 46, drawn to an aptamer, classified in Class 536, subclass 24.3.

V. Claims 19-22, 46, drawn to a primer pair, classified in Class 536, subclass 24.33.

VI. Claim 24, drawn to a method of diagnosing disorder with protein level, classified in Class 436, subclass 2.

VII. Claim 25-27, 54-55, drawn to a method of diagnosing disorder with gene sequence using sample DNA or RNA or PCR, classified in Class 435, subclass 6.

VIII. Claims 28-29, 32, 34 drawn to a composition, Class 514, subclass 44.

IX. Claims 28-29, drawn to a composition, Class 514, subclass 2.

X. Claims 28-29, drawn to a composition, Class 424, subclass 130.1.

XI. Claims 30, drawn to a method of treating disease with nucleic acid, Class 514, subclass 44.

XII. Claims 33, drawn to a pharmaceutical composition comprising a compound, classification could not be determined because no structure is provided.

XIII. Claims 36-45, drawn to a method of treating disease with a modulator, classification could not be determined because no common structure is provided.

XIV. Claims 47-49, drawn to a method of identifying a compound, Class 435, subclass 7.1.

XV. Claims 50-53, drawn to a method of producing an identified compound, classification could not be determined because no common structure is provided.

XVI. Claims 11-12, drawn to a transgenic organism, Class 800, subclass 2.

XVII. Claims 25-27, drawn to a method of diagnosing using immunological, Class 436, subclass 6.

XVIII. Claims 56, drawn to a method of diagnosing by quantifying RNA level, Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons.

The products of any one of the inventions I-V, VIII-X, XII and XVI, are distinct each from the other, because they are drawn to products having materially different structures and functions.

Inventions VI-VII, XI and XIII-XV and XVII-XVIII are distinct, each from the other, because they are drawn to processes having materially different process steps, which are practiced for materially different purposes.

The products of inventions I-V, VIII-X, XII and XVI, and the process of invention VI-VII, XI and XIII-XV and XVII-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the alternative inventions I-V, VIII-X, XII and XVI can be used in the alternative processs of Group VI-VII, XI and XIII-XV and XVII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications and recognized divergent subject matter, and the search required for any one of inventions I-XVII is not required for any other invention I-XVII, restriction for examination purposes as indicated is proper.

Part II: Markush Group of claim limitations

Furthermore, restriction to one of the following inventions is required under 35 USC 121:

The inventions as they pertain to one mutation position member of claims 1, 15 and 26 or generic claims which encompass the mutations.

This is a further requirement for restriction into separately patentable groups. Applicant must elect one member in order to be fully responsive. Because each disorder requires a unique search of the the literature databases and undue search burden would be imposed on the examiner if all of the members were examined on one patent application.

Furthermore, restriction to one of the following inventions is required under 35 USC 121:

The inventions as they pertain to one compound member of claims 37-42 and 52-53.

This is a further requirement for restriction into separately patentable groups. Applicant must elect one member in order to be fully responsive. Because each disorder requires a unique search of the the literature databases and undue search burden would be imposed on the examiner if all of the members were examined on one patent application.

Furthermore, restriction to one of the following inventions is required under 35 USC 121:

The inventions as they pertain to one disorder of claims 42-45.

This is a further requirement for restriction into separately patentable groups. Applicant must elect one member in order to be fully responsive. Because each disorder requires a unique search of the the literature databases and undue search burden would be imposed on the examiner if all of the members were examined on one patent application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-083535. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Pak/  
Primary Examiner, Art Unit  
August 12, 2008